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EXAMINER

DAVIS, KATHARINE F

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 04/08/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/635,370

Applicant(s)

RUBIN ET AL.

Examiner

Katharine F. Davis

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-- The MAILING DATE of this communication appears on the cover sheet with the corresponding address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 18 January 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 55,57-61,63-66,68,69 and 71-78 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 55,63-65,69,77 and 78 is/are rejected.
- 7) ☒ Claim(s) 57-61,66,68 and 71-76 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☒ Other: *Appendix B*.

### **DETAILED ACTION**

This Office Action is in response to the Reply filed on January 18, 2002. Claims 56, 62, 67 and 70 have been cancelled. Claims 55, 57-61, 63-66, 68, 69 and 71-78 are pending in the instant application.

The objections to claims 62, 67 and 70, the rejection of claims 56, 62, 67 and 70 under 35 U.S.C. 112, first paragraph, the rejection of claim 67 under 35 U.S.C. 102(b), the rejection of claims 62, 67 and 70 under 35 U.S.C. 102(e) (Peck *et al.*) and the rejection of claims 62, 67 and 70 under 35 U.S.C. 102(e) (Hoffman *et al.*) have all been withdrawn in view of the cancellation of the claims.

The objections to claims 68 and 72, the rejection of claims 55, 57-61, 63-66, 68, 69 and 71-78 under 35 U.S.C. 112, first paragraph, the rejections of claims 73 and 76 under 35 U.S.C. 112, second paragraph, the rejection of claims 55, 61, 64-66, 68, 69, 71, 74 and 75 under 35 U.S.C. 102(b), the rejection of claims 55, 61, 63-66, 68, 69, 73, 74 and 76 under 35 U.S.C. 102(e) (Peck *et al.*) and the rejection of claims 55, 61, 66, 69, 72, 74 and 75 under 35 U.S.C. 102(e) (Hoffman *et al.*) have all been withdrawn in view of the amendments to the claims and the remarks presented by the Applicants in the Reply filed on January 18, 2002.

The Reply filed on January 18, 2002 was subjected to the United States Postal Service irradiation process, see attached Appendix B.

### ***Specification***

The disclosure is objected to because of the following informalities: In the Brief Description of the Drawings each panel or drawing containing multiple panels must be referred

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to as a separate figure. The first line of each description must refer to each separate figure (e.g., Figures 3A-3G). Correction is required for Figures 3-6, 8 and 46. This objection was not addressed in the Reply filed on January 18, 2002.

Additionally the specification is objected to because the Brief Description of the Drawings section contains no descriptions of Figures 41-60. Applicants indicate that the specification has been amended to include proper descriptions for all figures (see page 8 of the Reply filed on January 18, 2002) however it appears that no such amendments have been made.

Therefore both of the above objections to the specification are maintained for both the reasons above and the reasons made of record in the previous Office Action mailed on July 30, 2001.

It is noted that the Sequence Listing filed on January 18, 2002 (both computer-readable and paper forms) has been entered. The STIC made the following correction: deletion of the non-ASCII text at the end of the files.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 55, 63-65, 69, 77 and 78 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 3-5, 8, 15, 25 and 26 of U.S. Patent No. 6,326,201. Although the conflicting claims are not identical, they are not patentably distinct from one another. Claims 55, 63-65, 69, 77 and 78 are drawn to a method for preparing a substantially pure non-adherent population of progenitor cells comprising the steps as recited in claims 55 and 69 thereby obtaining a substantially pure non-adherent progenitor cell population that is at least about 50% pure (claim 55) or at least about one-hundred (claims 69 and 78 as applied to the method of claim 55) or a thousand-fold (claim 77) enriched from the original population. The progenitor cell population is obtained from a cell suspension of animal tissue selected from pancreatic tissue, pancreatic ductal tissue, liver tissue and dermis. The cell suspension is obtained by mechanical or enzymatic disruption of the animal tissue and said cell suspension is treated with a growth factor preparation comprising epidermal growth factor (EGF), transforming growth factor (TGF), hepatocyte growth factor (HGF), fibroblast growth factor (FGF) and insulin-like growth factor (IGF); for example. Claims 1, 3-5, 8, 15, 25 and 26 of U.S. Patent No. 6,326,201 are drawn to a method of isolating progenitor cells comprising the

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steps as recited in claim 1. The population of progenitor cells is obtained from pancreatic ductal tissue which has been mechanically or enzymatically disrupted. The progenitor cells are non-adherent cells grown to confluence that can be treated with an agent such as a growth factor. Claims 25 and 26 recite epidermal growth factor (EGF), transforming growth factor (TGF), hepatocyte growth factor (HGF), fibroblast growth factor (FGF) and insulin-like growth factor (IGF) as growth factor agents. It is clear from comparison of both sets of claims that the claimed methods for obtaining progenitor cell populations are essentially the same, the differences being that the instant claims recite a broader range of tissues that the progenitor cell population can be obtained from including dermis and liver tissues in addition to pancreatic ductal tissue and additionally the instant claims recite specific ranges of purity and enrichment of the claimed progenitor cell populations. It is noted from review of other claims of U.S. Patent No. 6,326,201 that the method of isolating a population of progenitor cells is intended to produce compositions of progenitor cells which can be induced to form functional pancreatic tissues. It is known in the art that progenitor cells have a bias to differentiate into their tissue of origin, for example pancreatic progenitor cells become mature pancreatic cells. Pure and/or enriched cell populations are also known in the art to be advantageous for research purposes, in the instant situation, the purer (or more enriched) a population of progenitor cells is the more likely the population is to be successfully induced by a growth factor preparation to become a cell population with the desired traits. One of ordinary skill in the art would be motivated to produce the purest and/or most enriched cell population as possible and thus it is considered obvious when carrying out methods of preparing and/or isolating populations of progenitor cells to purify and/or enrich said populations. Therefore, claims 55, 63-65, 69, 77 and 78 of the instant application and claims 1,

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3-5, 8, 15, 25 and 26 of U.S. Patent No. 6,326,201 are not patentably distinct. If a patent resulting from the instant claims was issued and ownership of the issued patent was transferred to an assignee different from the assignee holding the 6,326,201 patent, the result would be that two different assignees would hold a patent to the claimed invention and thus there would be the possibility of harassment by multiple assignees.

### *Conclusion*

Claims 55, 63-65, 69, 77 and 78 are rejected. Claims 57-61, 66, 68 and 71-76 are objected to as being dependent upon rejected base claims but would be allowable if re-written in independent form including all of the limitations of the base claims and intervening claims. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Katharine F. Davis whose telephone number is (703) 605-1195 with direct desktop RightFax (703) 746-5199. The examiner can normally be reached on Monday-Friday (8:30am-5:00pm). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached on (703) 305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 305-1935 for After Final communications. Any inquiry of a general nature or any inquiry concerning the formalities of this application should be directed to Patent Analyst Tracey Johnson whose telephone number is (703) 305-2982.

Katharine F. Davis  
April 4, 2002

DAVID GUZO  
PRIMARY EXAMINER  
